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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,948

12/12/2003

Jong Kil

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3699

36802

7590

05/04/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

SMITH, STEPHANIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/735,948	Applicant(s) KIL ET AL.	
	Examiner Stephanie Smith	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12 December 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a method and system for emulating a surface EKG, classified in class 600, subclass 510.
- II. Claims 17-25, drawn to drawn to a method and system for emulating a surface EKG using two sensing circuits, classified in class 600, subclass 509.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination as claimed does not require using one sensing circuit, but requires sensing circuitry for the atria and ventricles. The subcombination has separate utility such as not requiring sensing circuitry for the atria and ventricles, but requiring one sensing circuit.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: Embodiment I comprising identifying far-field atrial and ventricular signals and concatenating the far-field signals; Embodiment II comprising concatenating by determining a value representative of the peak magnitude of the far-field atrial and ventricular signals and forming a ratio of the magnitudes; Embodiment III comprising identifying near-field atrial and ventricular signals and concatenating the near-field signals; and Embodiment IV comprising concatenating by determining a value representative of the peak magnitude of the near-field atrial and ventricular signals and forming a ratio of the magnitudes. The species are independent or distinct because each species is directed to a patentably distinct method of concatenating.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Derrick Reed on April 21, 2006 a provisional election was made without traverse to prosecute the invention of a method and system for emulating a surface EKG, claims 1-16, and Embodiment I comprising identifying far-field atrial and ventricular signals and concatenating the far-field signals, claim 3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-8, and 17-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Electrodes are inferentially included. It is suggested to positively recite or functionally recite the electrodes. If the Applicant wants to claim the electrodes, it is suggested to first positively recite the electrodes before they are used. If the electrodes are being functionally recited it is suggested to use "for" or "adapted to..."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedberg et al (U.S. 5740811). Referring to claims 1, 2, and 15-16, Hedberg et al. teach a method and apparatus that comprises an implantable cardiac stimulation device having an atrial and ventricular electrode and sensing atrial and ventricular signals. The signals are combined and a surface ECG is obtained in an extracorporeal signal processing device (see column 2, lines 55-67 and column 3, lines 1-5 and column 4, lines 40-49 and figure 1). While Hedberg et al. do not explicitly state that the device and method concatenate the atrial and ventricular signals, the Examiner is considering the definition of concatenating to be the joining of two strings or linking together. Regarding

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claim 9, Hedberg et al. teach sensing atrial and ventricular signals using unipolar sensing by employing the electrodes in combination with the housing of the device (see column 4, lines 40-49). With regards to claim 10, Hedberg et al. teach a right atrial tip electrode and a right ventricular tip electrode (see figure 1 and column 4, lines 40-42 and lines 52-53). With reference to claim 11, Hedberg et al. teach that local noise is filtered out of the signals (see column 5, lines 27-29 and lines 46-48), and referring to claim 12, Hedberg et al. teach combining by addition signals received from different electrodes (see column 6, lines 54-57). Regarding claim 13, also teaches using the emulated EKG to adjust parameters controlling the implant (see column 2, lines 13-22). Regarding claim 14, Hedberg et al. teach that the components that generate the synthesized ECG can be completely contained within an implantable unit (see column 2, lines 65-67 and column 3, line 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hedberg et al. in view of Duffin (U.S. 5193550). Hedberg et al. teach sensing atrial and ventricular signals and concatenating them to yield the emulated EKG. Hedberg et al. do not teach sensing far-field atrial and ventricular signals. Duffin does teach sensing far-field atrial and ventricular signals in the ventricular and atrial chamber, respectively (see figure 1 and column 8, lines 37-43). Duffin further teaches that the far-field atrial and ventricular signals aid in categorizing the source and type of tachyarrhythmia detected (see Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method and device for simulating an ECG as taught by Hedberg et al. with the sensing of far-field waves taught by Duffin in order to categorize the source and type of tachyarrhythmia detected.

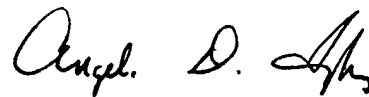
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRS 5/1/06
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